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July 14, 2020

VIA ECF
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this letter on behalf of the Plaintiffs in advance of the July 15, 2020 status conference.

1. Status of Manufacturer Document Productions.

Plaintiffs request an update on the status of the manufacturers' document and ESI productions, including to confirm that the requested prioritization will be occurring, and to alert the Court and the parties to any issues, so that they can be addressed promptly.

2. Teva Belated Disclosure of Intent to Utilize a Form of Technology-Assisted Review in addition to Search Terms Review.

On July 1, 2020 Teva notified the Plaintiffs for the first time of its intention to apply a form of technology-assisted review, specifically an active learning application known as Brainspace Continuous Multimodal Learning ("CMML"), for custodial document review and production. More directly, this is a second document review process which they intend to layer on top of the search terms process that was ordered last year, and then heavily re-litigated again recently. Thus, after an untimely, blunt force attack over the past several months intended to narrow the scope of custodial documents collected through the search terms, this additional process would alter the expected review and flow of documents produced – in contravention of the Plaintiffs' already established prioritization of what should be targeted and produced first, and permit Teva to classify an unlimited quantity of the documents identified by the search terms as unlikely relevant, and thus with no need to be reviewed, let alone produced.

To be clear, the segregation of a potentially massive quantity of documents not meriting review, and thus to be discarded, is a key tenet of this proposed process, even though Teva disingenuously suggests in its July 1, 2020 letter that they will make this decision later: "If, at some point, the CMML system is indicating that there is a population of documents unlikely to be responsive (such that it will be unduly burdensome for the Teva Defendants to review them), we will inform Plaintiffs of the same." Copies of Teva's successive letters dated July 1, 2020, July 6, 2020, July 10, 2020, and July 12, 2020 regarding the CMML issue are attached hereto as Exhibit A; the quoted language is found on page 2 of the July 1, 2020 letter, and repeated in the subsequent letters. Plaintiffs objected by email, and on July 6, 2012 Teva responded, and reiterated, "Put differently, the Teva Defendants are currently reviewing all documents if or until the CMML platform indicates such review would no longer be efficient and/or reasonable." See Exhibit A. Of course, this is just a set up for a significant dispute later. The parties had a telephone conference to discuss this issue on July 8, 2020, and Teva provided supplemental information

on July 10, 2020, reiterating their intention to proceed, and Plaintiffs responded and objected once again. Teva again wrote on July 12, 2020 to inform Plaintiffs that they intended to proceed, and Plaintiffs advised that this issue would be raised with the Court.

As a threshold matter, it is astonishing that Teva felt it was appropriate to keep secret from the Court and the Plaintiffs its intention to layer a second review process on top of the search terms, until after the search terms had been finalized with much effort for the second time, and in the face of the imminent start to the rolling production. Teva took the position during the recent battle over the search terms that the search terms had to be narrowed because too many documents were being collected, but never suggested that CMML would be used to review and further narrow the collected documents. Thus, all of the briefing and negotiations were conducted on the false premise that Teva intended to proceed as had been represented, to use the search terms to collect, followed by manual review and production of the documents, as all of the other Defendants are proceeding – and Plaintiffs made concessions on the breadth of the search terms in reliance on this posture.[1]

Teva's position is deeply flawed in this procedural posture. Teva touts CMML as a more advanced version of conventional TAR, to be applied to the document sets created by application of the search terms.[2] Of course, search terms and technology assisted review are alternatives in this setting. Even the vendor of the application touts CMML as a superior **alternative** – not an adjunct - to use of search terms, stating in its marketing "white papers" that: (1) "Finding documents once meant keywords and complex query syntax, with all the limitations that brought." and (2) "A stop gap measure was to only consider documents that matched a keyword filter." See: Brainspace marketing whitepapers produced by

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[1] In requesting and obtaining a lengthy discovery extension earlier this year, defense liaison counsel painted the picture of the defense's document reviewers sitting at computers reviewing the documents for relevance and privilege as part of the production process. Teva certainly did not speak up to indicate that its different plan, to use automated review.

[2] As far as Plaintiffs are aware, the Brainspace product has never been used in multi-district litigation nor any litigation similar to this one.

Teva, attached hereto as Exhibit B, specifically at page 12 and page 2 respectively. Teva's intention to use CMML should have been disclosed at the earliest possible time. That was last year before the choice was made to proceed with search terms as the review methodology for Teva custodial documents and codified in an Order, so that the process could be negotiated and disputes ruled on at that time. The failure to do so then, and then again while participating in the defense's 2020 attack on the ordered search terms, is very troubling.

Plaintiffs agree that machine-learning software can be useful and can be a reasonable alternative to the application of search terms to collect documents for production in some situations. The ESI Protocol here provides for this possibility and directed the Defendants to raise and discuss this potential alternative with the Plaintiffs before employing it, as this would obviously require a robust meet and confer process. Plaintiffs asked multiple times over the past year if the Defendants intended to utilize this alternative, and no Defendant ever indicated that this would be utilized. Nobody imagined that Teva was secretly harboring this intent. Plaintiffs shared their displeasure at having this process sprung on them at literally the last minute, as it would alter the expected flow of document production and likely limit the universe of documents to be produced, among other things, but agreed to meet and confer.

The more granular problems with Teva's proposal, addressed in more detail below, include Teva's refusal to share with Plaintiffs their definition of a "responsive" document, which is the linchpin to selecting documents as the system operates and learns the parameters for selection. Teva deemed this information privileged, and refused to allow Plaintiff any visibility to the actual application, or frankly to engage in any dialogue to allow Plaintiffs any input or visibility to the review. For example, only Teva would determine whether the process was under or over-inclusive and what modifications to make in real time. It is not an overstatement to say that the guts of the proposed application of CMML here are to be hidden in a black box with no input from Plaintiffs. This stands in stark contrast to the lines of cases recognizing the need for robust collaboration if such a process is to be fair and effective (see below).

Another major problem is that the flow of production of documents would be determined by the CMML review process, rather than the ordered focus on Plaintiffs' requests for prioritization. Plaintiffs assumed that Teva would comply with the expectations of the Court and target the categories of documents and custodians identified by Plaintiffs, but that is not what this is. Instead, the flow of document production would be determined by the machine-based review, leading to an uneven production and the likelihood that key responsive documents would be pushed to the end of the production, if produced at all. Perhaps most important, **documents not meeting the secret definition of responsiveness (despite being identified by the search terms) would then be pushed aside and some undetermined number would be grouped accordingly and not even be reviewed at all**. To be clear, it is a virtual certainty that Teva will identify relevant documents requiring production that will fall into this black hole of non-production, triggering a significant dispute.

Teva provided several citations to cases in its letters, in its effort to demonstrate to Plaintiffs that its proposal was sound. However, the four cases cited actually contradict its position or are completely off point. Starting with the last case cited, Teva cited *Progressive Cas. Ins. Co. v. Delaney*, 2014 WL 3563467 (D. Nev. July 8, 2014) in its July 10, 2020 letter for the general proposition that, "Predictive coding has emerged as a far more accurate means of producing responsive ESI in discovery. Studies show it is far more accurate than human review or keyword searches which have their own limitations." *Id*. at *6 (mistakenly cited as *6). First, if Teva truly believed that to be so, why did they agree to a search terms process. Moreover, aside from the generic boilerplate statement quoted, it is as if Teva did not read the case before citing to it. The holding fully supports Plaintiffs' position here, as the Court refused to allow the defendant to proceed to layer a technology assisted review on top of a document set already narrowed from 1.8 million pages to 545,000 pages by application of search terms. The case reads as a playbook for why Teva should be similarly precluded here. First, based on the attempt to impose this methodology at the last minute on top of a search term methodology that had been heavily litigated.

Second, based on Teva's unilateral black box approach, including a refusal to provide the definition of responsiveness, or key data, and refusal to involve Plaintiffs in the process at all. This flies in the face of settled principles requiring cooperation – especially in the context of a heavily litigated MDL: "The cases which have approved technology assisted review of ESI have required an unprecedented degree of transparency and cooperation among counsel in the review and production of ESI responsive to discovery requests . . . the courts have required the producing party to provide the requesting party with full disclosure about the technology used, the process, and the methodology, including the documents used to 'train' the computer." *Id*. at *10, citing in part *In re Actos (Piglitazone-Prods.Liab.Lit.)*, No. 6:11-md-2299, slip op. (W.D. La. July 7, 2012). The conclusion was that the defendant could not apply the machine based review to further limit the document set collected with the search terms, and the defendant had to serve every document hit by the search terms. *Id*. at 12.

In its July 6, 2020 letter, Teva cited another case that strongly supports Plaintiffs' position. In *Rio Tinto PLC v. Vale S.A. et al.*, 306 F.R.D. 125 (S.D.N.Y. 2015), the Court was addressing a commercial dispute, not a complex MDL with varied layers of relevant document categories. Moreover, the parties **agreed** to the TAR protocol, both parties were utilizing the same machine based learning protocol **from the outset**, and the parties agreed to share seed sets of documents, and to allow the requesting party to obtain quality control reports during the reviews. In the course of the case, the Court cited to a line of cases requiring collaboration including involvement of the requesting party in the coding and quality control process, often by agreement. This includes *In re Actos*, 2012 WL 7861249 (W.D. La. July 27, 2012), characterized as follows: "the parties' protocol had 'experts' from each side simultaneously reviewing and coding the seed set." *Id*. at 128. The other two cases cited involved requests by the plaintiffs to compel the use of TAR rather than search terms, from the outset, and in both cases the Courts refused to compel the use of TAR. See *In re Mercedes-Benz Emissions Litig.*, 2020 WL 103975 (D.N.J. Jan. 9, 2020); *Hyles v. New York City*, 2016 WL 4077114 (S.D.N.Y. Aug. 1, 2016). That is not this case.

As set forth, Plaintiffs have serious technical concerns with Teva's intended implementation of predictive coding. Plaintiffs' concerns extend to the inability of Teva to prioritize sets of documents and custodians for review that Plaintiffs have indicated are chief to issues of import in the litigation, the unwillingness of Teva to work transparently with Plaintiffs in the configuration and testing of their software, and the late attempt to lay a foundation for a future effort by Teva to preclude significant numbers of documents for review based upon some to be determined relevancy threshold and discard point. There are many problems with this belated proposal.

Despite Brainspace highlighting in its white paper that a key benefit to the product is being able to define multiple "choice" tags, Teva has indicated in the meet and confer that they will only define and code a single tag for each document, *i.e.* responsive/not responsive. See Brainspace CMML Whitepaper at p.6. Teva's configuration choice is thus contrary to the vendor's own recommendations. In contrast, the parties spent months negotiating and then re-negotiating search terms because this litigation resists simplistic categorization of relevant documents. There is simply not enough homogeneity across the entire document set to find (even with the most sophisticated AI learning) a pattern indicative of relevance. Since Brainspace employs an active learning system whereby the next set of documents shown to a given reviewer are influenced by the documents previously marked relevant, Teva's single choice tag is clearly going to sharply bias to the more numerous categories of relevant documents. That translates into the likelihood of documents which may be the most crucial to the litigation including reports, emails, etc. being pushed to the back of the pack so to speak, to the final review sets and thus to later productions.

Teva's configuration of their predictive coding in the simple up/down choice tag also gives the Brainspace system insufficient input into the two factors necessary to prioritize the review. First, why the document was relevant. Second, how relevant was the document. Without defining and coding a multitude of choice tags, the machine will not be able to prioritize documents that are more relevant on the most relevant issues. Instead, it will default to relevant documents that are most numerous. While

these common relevant documents would be statistically almost certainly the most common component of nearly any production methodology, Teva's choice of configuration unduly preferences them at the expense of diversity simply by denying the Brainspace system complete input.

Due to the nature of their proposed process, and as discussed on the July 8th telephonic meet and confer, Teva will not offer Plaintiffs any transparency into their relevancy decision making. With traditional TAR, Plaintiffs would get to review rejected documents in a seed set, working with Defendants to find a balance across the production. With Brainspace, since it is continually learning, the initial custodians and documents reviewed, along with the individual decisions of relevant/not made by each reviewer, will strongly influence the sets of documents shown to reviewers on subsequent custodians. Since Teva has stated that none of those review decisions will be shared with Plaintiffs, Plaintiffs have no transparency into the process. Indeed, even if Teva were to share, since the software is continually learning, Plaintiffs would need to be engaged throughout the entire review. Any software system is only as good as its inputs. In fact, Teva has not even disclosed whether its reviewers would know the relevance scoring Brainspace predicted on each document, which could bias the ongoing reviews.

Teva has also failed to disclose any plans to Plaintiffs for how they would conduct continuous quality control on their system. Due to the review of certain types of custodians before other types, who may well be privy to overlapping documents but for different purposes, *i.e.* custodians involved in testing versus custodians involved in regulatory affairs, Plaintiffs believe that any active machine-learning system would have to be continuously revalidated, with Plaintiffs' input, in a formalized manner to prevent selection bias on subsequent collection sets.

Furthermore, since Teva purports to undertake the predictive coding review to save money and time, Plaintiffs expect that Teva will eventually approach the Court with a relevancy threshold and discard point. Teva will argue that their software has ranked documents that have yet to be reviewed as unlikely to be relevant with a proposal that all documents scored below a certain point not be subject to

review. They will attempt to back that up statistically by pulling random samples of documents which of course will be statistically likely at that point to support their position. For the reasons aforementioned, Teva's configuration choice (single vector approach) makes it much more likely that rarer, but highly relevant documents, will be suppressed from the batches presented to reviewers in a prioritized review. These highly relevant documents may be shorter documents that simply did not have enough linguistic density for Brainspace to promote for review, or they might contain image data that Brainspace did not have sufficient patterns to appreciate, or they might be multi-page documents where one section is key and critical to the case, but the rest of the document relates to non-relevant products. In short, the deck will have been stacked to support the desired conclusion, and the extent of the preclusion cannot be foreseen.

This may have been a feasible approach to begin discussing a year ago, when there was time to work through all of these issues in the balanced fashion required by this Court. It is simply too late to introduce a new search methodology into this litigation as a tool for production of documents, especially where Teva offers Plaintiffs no involvement or even visibility to the granular details of the review and will inevitably seek to use this methodology to exclude documents from review, let alone production. If done right, from the start, this would have required an extensive meet-and-confer process and extensive cooperation as to many details of the process. If permitted now, the parties will have to spend valuable time and resources navigating a complex meet and confer just as the documents are supposed to roll out based on Plaintiffs' prioritization requests, which would undoubtedly result in disputes requiring briefing and the Court's intervention. This would be a massive and unwarranted distraction. The following issues and many others would have to be addressed: (1) ensuring complete timely reviews of each custodian, (2) re-examination of documents marked non-relevant, (3) continuous sampling of rejected documents, (4) addressing contextual diversity in subsequent batches, (6) ensuring initial second checks by senior reviewers, (5) not applying automatic training to subsequent custodians, (6) ensuring that there is a large

enough set to support CMML, and (7) not using CMML for/re-review of certain categories of documents where relevance may be near impossible to recognize outside of context, ex: very short emails, spreadsheets. **Finally, under no circumstances can Teva be permitted to segregate documents as presumptively not requiring review, let alone production**.

For all of these reasons, Plaintiffs request that Teva be precluded from utilizing CMML for any purposes related to the review for production of the documents collected through application of the Court Ordered search terms.

3. Retail Pharmacy Document Productions.

The Retail Pharmacy Defendants contacted Plaintiffs requesting agreement to a 60-day extension to complete their document production. In light of the Court's denial of that request during the hearing, and keeping in mind the months of lead time prior to the Court's decision, Plaintiffs did not agree. However, Plaintiffs did agree to confer with liaison counsel to the extent input or information is needed to facilitate the productions. A copy of Plaintiffs' letter to Defendants with regard to the request for the extension is attached hereto as Exhibit C.

Respectfully,

Adam M. Slater